IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Keith W. Van Meter and Frederick A. Kriedt

DATE: March 3, 2005

SERIAL NO.:

FOR:

10/019,548

EXAMINER: Eric Frank Winakur

INTERNATIONAL APPLICATION NO. PCT/US00/10968

Art Unit: 3716

INTERNATIONAL APPLICATION FILED: April 20, 2000

"HYPERBARIC RESUSCITATION SYSTEM AND METHOD"

ATTORNEY DOCKET NO.: Attorney Docket No. P99210USWO (04215.1P3.USWO)

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES **BRIEF OF APPELLANT**

Mail Stop Appeal Brief - Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sirs:

On 24 August 2004, the Examiner finally rejected Claims 24-26, 28-32, 40, 41, and 43-54 of the above-referenced patent application. A Notice of Appeal was filed on 23 December 2004, and was received by the USPTO on 3 January 2005. This brief, required by 37 C.F.R. § 41.37(a), is due by 3 March 2005 (see 37 C.F.R. § 1.8(a)(2) and MPEP § 512 (Eighth Edition, Revision 2, May 2004)); it is in the form required by 37 C.F.R. § 41.37(c).

CERTIFICATE OF MAILING

I hereby certify that this Appeal Brief is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 3rd day of March, 2005.

03/08/2005 HALI11	00000040 10019548		
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		Seth M. Nehrbass, Reg. No. 31,281	

(i) REAL PARTY IN INTEREST:

The real parties in interest are the applicants and Baromedical Research Institute, Ltd. (a Louisiana corporation).

(ii) RELATED APPEALS AND INTERFERENCES:

There are no related appeals or interferences.

(iii) STATUS OF CLAIMS:

Claims 1 through 23, 27, 33-39, and 42 have been cancelled. Claims 24-26, 28-32, 40, 41, and 43-54 are pending. Claims 24-26, 28, 30, 32, 40, 43, 44, 46, 48, 49, and 51 were rejected under 35 U.S.C. § 102(b) as being anticipated by Jöbsis. Claims 24, 29, 31, 41, 45, 47, and 50-54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chance et al.

The rejection of Claims 24-26, 28-32, 40, 41, and 43-54 is being appealed.

(iv) STATUS OF AMENDMENTS:

No amendments after the final Office Action have been filed..

(v) SUMMARY OF CLAIMED SUBJECT MATTER:

As required by 37 C.F.R. § 41.37(c)(1)(v), Applicant has read some of the appealed claims on the specification and drawings. These claims follow.

- 24. (previously presented) A system comprising:
- (a) a light source (202 see Figure 14);
- (b) a pickup optode unit (204) for detecting light from the light source;
- (c) a spectrophotometer (300 see Figure 20) coupled to the pickup optode unit for sensing and recording a NIR wavelength interval including cytochrome oxidase, water and hemoglobin data;
- (d) a personal computer (311 see Figure 20) with a software algorithm (see Figure 23 and page 25, line 24 through page 26, line 15) to separate the cytochrome oxidase, water and hemoglobin data for evaluation and display.
- 26. (previously presented) A method of using the system of claim 24 to monitor the change of any natural or manmade chromophore (see page 17, lines 23-26 and page 25, line 24 page 26, line 15) existing in a person's brain to assist in the diagnosis or treatment of a neurological or psychotic

disorder, comprising:

using the light source (202 - see Figure 14) to illuminate a person's cerebral tissue; using the pickup optode unit (204) to detect light from the person's cerebral tissue;

using the spectrophotometer (300 - see Figure 20) to sense and record a NIR wavelength interval including cytochrome oxidase, water and hemoglobin data;

using the personal computer (311 - see Figure 20) and the software algorithm (see Figure 23 and page 25, line 24 through page 26, line 15) to separate the cytochrome oxidase, water and hemoglobin data for evaluation.

- 28. (previously presented) The invention of claim 24, wherein the spectrophotometer monitors relative changes in redox levels in real-time (see page 7, lines 9-21)
- 29. (previously presented) The invention of claim 24, wherein the software algorithm uses Fourier transforms (see page 19, line 20, through page 21, line 12) in analyses of near infrared data obtained from the spectrophotometer.

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL:

- (A) Claims 24-26, 28, 30, 32, 40, 43, 44, 46, 48, 49, and 51 were rejected under 35 U.S.C. § 102(b) as being anticipated by Jöbsis.
- (B) Claims 24, 29, 31, 41, 45, 47, and 50-54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chance et al.

(vii) ARGUMENT:

(A) Claims 24-26, 28, 30, 32, 40, 43, 44, 46, 48, 49, and 51 are patentable over Jöbsis under 35 U.S.C. § 102(b).

Claims 24-26, 28, 30, 32, 40, 43, 44, 46, 48, 49, and 51 were rejected under 35 U.S.C. § 102(b) as being anticipated by Jöbsis. Applicants respectfully traverse this rejection.

Applicants cited Jöbsis and Chance and were aware of them when drafting the claims on appeal. Jöbsis does not anticipate these claims.

Jöbsis does not anticipate these claims because Jöbsis does not disclose "(d) a personal computer with a software algorithm to separate the cytochrome oxidase, water and hemoglobin data for

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evaluation and display".

Jöbsis likewise does not render obvious the claims of the present invention, alone or in combination with Chance et al.

Jöbsis indicates that the field of the invention is to extract the concentration of a dilute component in a light radiation scattering environment. That is not the field of determining the concentration of cytochrome oxidase in vivo. The true field is to extract the concentration of a very dilute component (cytochrome oxidase) within a dilute component (hemoglobin) within a light scattering media (tissue). Although the cytochrome oxidase is not physically located in the hemoglobin, the light can not distinguish the precise location (i.e. whether it is in the hemoglobin or in the light path that goes through everything. Chance et al. points this out in its one reference to cytochrome where it says it is 20 times less strong of a signal therefore does not play into the equation.

Jöbsis only mentions aa3 in column 17 at lines 52-64 where he indicates that only two more wavelengths need to be added. He points out that water is not in the neighborhood to allow the path length calculation to be done but hemoglobin can be used to do bridging. It appears that nowhere else in the patent does he define what bridging is.

Also, Jöbsis makes a point throughout the patent description that the object of his device is to obtain an unknown dilute component in a known reference component. As Chance et al. and the present inventors point out, in order to measure aa3 in vivo, one must extract a very dilute unknown component (aa3) from a dilute component (Hb) from a known component (water in the tissue).

CLAIM 26:

Jöbsis does not anticipate claim 26 because it does not use a personal computer and a software algorithm to separate cytochrome oxidase, water and hemoglobin data for evaluation.

CLAIMS 29 AND 45

Jöbsis does not anticipate claim 29 or 45 because Jöbsis uses the Beer Lambert equation and these claims specify Fourier transforms.

(B) Claims 24, 29, 31, 41, 45, 47, and 50-54 are patentable over Chance et al. under 35 U.S.C. § 103(a).

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Claims 24, 29, 31, 41, 45, 47, and 50-54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chance et al. Applicants respectfully traverse this rejection.

First, the Office Action indicates that Chance et al. suggests that the instrument disclosed therein is suitable for cytochrome oxidase (aa3). Applicants respectfully disagree. The only place that Chance et al. mentions cytochrome oxidase (aa3) is in column 23, lines 39-53 where it says that the signal is 1/20 of Hb and therefore has no effect. Therefore, Chance et al. does not render these claims obvious, as one would not consider using Chance et al. to separate cytochrome oxidase, water and hemoglobin data for evaluation and display.

CLAIMS 29 AND 45

Chance et al. does not render claim 29 or 45 unpatentable. Chance et al. uses a Fourier transform, but for a completely different reason. The present inventors use Fourier transforms to separate the cytochrome oxidase signal from the hemoglobin signal (which Chance et al. says is impossible) and Chance et al. uses it to look for changes between two different signals. The application is completely different. An analogy would be, because Chance et al. uses subtraction to measure changes in two different measurements, it is obvious that we could use subtraction to remove the hemoglobin effect from the cytochrome signal.

CONCLUSION:

For the foregoing reasons, applicant respectfully submits that all claims remaining in the application are allowable. A Notice of Allowance is hereby respectfully requested.

TELEPHONE CONFERENCE INVITATION:

Should the Examiner or any member of the Board feel that a telephone conference would advance the prosecution of this application, he is encouraged to contact the undersigned at the telephone number listed below.

<u>PETITION FOR EXTENSION OF TIME:</u>

Applicant hereby petitions the Commissioner under 37 C.F.R. § 1.136 for any extension of time necessary to render this Appeal Brief timely filed, and asks that the fee for any such extension be charged to Deposit Account No. 50-0694.

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FEES:

A \$250 check for the fee required by 37 C.F.R. § 41.37(a)(2) and § 41.20(b)(2) is enclosed. Please charge any additional fees due or credit any overpayment to Deposit Account No. 50-0694.

Respectfully submitted,

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(viii) CLAIMS APPENDIX:

CLAIMS ON APPEAL:

- 24. (previously presented) A system comprising:
- (a) a light source;
- (b) a pickup optode unit for detecting light from the light source;
- (c) a spectrophotometer coupled to the pickup optode unit for sensing and recording a NIR wavelength interval including cytochrome oxidase, water and hemoglobin data;
- (d) a personal computer with a software algorithm to separate the cytochrome oxidase, water and hemoglobin data for evaluation and display.
 - 25. (original) The system of claim 24, wherein the light source is a stabilized pulsed light.
- 26. (previously presented) A method of using the system of claim 24 to monitor the change of any natural or manmade chromophore existing in a person's brain to assist in the diagnosis or treatment of a neurological or psychotic disorder, comprising:

using the light source to illuminate a person's cerebral tissue;

using the pickup optode unit to detect light from the person's cerebral tissue;

using the spectrophotometer to sense and record a NIR wavelength interval including cytochrome oxidase, water and hemoglobin data;

using the personal computer and the software algorithm to separate the cytochrome oxidase, water and hemoglobin data for evaluation.

- 28. (previously presented) The invention of claim 24, wherein the spectrophotometer monitors relative changes in redox levels in real-time.
- 29. (previously presented) The invention of claim 24, wherein the software algorithm uses Fourier transforms in analyses of near infrared data obtained from the spectrophotometer.
 - 30. (previously presented) The invention of claim 24, wherein: the spectrophotometer includes:

a background pickup device which receives photons that have traversed a patient's scalp and skull but not deep enough to reach the patient's cerebral cortex,

> a sample pickup device that is positioned to receive photons that have traversed the patient's scalp, skull dura matter, and pia, and

the background signal is subtracted from the sample signal by the software algorithm to result in a signal representing the patient's cerebral cortex.

- 31. (original) The system of claim 24, wherein the light source is a quartz halogen 150 watt light source.
- 32. (original) The system of claim 24, wherein the NIR wavelength interval is about 700-1050 nm.
- 40. (previously presented) The invention of claim 24, comprising means for monitoring oxygen in cerebral tissue by monitoring cytochrome oxidase in a patient's cerebral tissue.
- 41. (previously presented) The invention of claim 24, comprising means for monitoring oxygen in cerebral tissue is monitored by monitoring the redox ratio of cytochrome oxidase in the cerebral tissue.
- 43. (previously presented) The method of claim 26, wherein the light source is a stabilized pulsed light.
- 44. (previously presented) The method of claim 26, wherein the spectrophotometer monitors relative changes in redox levels in real-time.
- 45. (previously presented) The method of claim 26, wherein Fourier transforms are used in analyses of near infrared data obtained from the spectrophotometer.
 - 46. (previously presented) The method of claim 26, wherein: the spectrophotometer includes:

a background pickup device which receives photons that have traversed the patient's scalp and skull but not deep enough to reach the patient's cerebral cortex,

a sample pickup device that is positioned to receive photons that have traversed the patient's scalp, skull dura matter, and pia, and

the background signal is subtracted from the sample signal by the algorithm to result in a signal representing the patient's cerebral cortex.

- 47. (previously presented) The method of claim 26, wherein the light source is a quartz halogen 150 watt light source.
- 48. (previously presented) The method of claim 26, wherein the NIR wavelength interval is about 700-1050 nm.
- 49. (previously presented) The method of claim 26, wherein oxygen in cerebral tissue is monitored by monitoring cytochrome oxidase in the cerebral tissue.
- 50. (previously presented) The method of claim 26, wherein oxygen in cerebral tissue is monitored by monitoring the redox ratio of cytochrome oxidase in the patient's cerebral tissue.
- 51. (previously presented) The system of claim 24, further comprising connecting fiber optics attached to the light source.
- 52. (previously presented) The system of claim 51, further comprising a near infrared band pass filter and wherein the spectrophotometer is a dual wave interval spectrophotometer.
- 53. (previously presented) The system of claim 24, further comprising a near infrared band pass filter.
- 54. (previously presented) The system of claim 24, wherein the spectrophotometer is a dual wave interval spectrophotometer.